



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1159]

Food and Drug Administration Categorization of Investigational Device Exemption Devices to Assist the Centers for Medicare and Medicaid Services with Coverage Decisions; Draft Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions." This guidance modifies FDA's current policy on categorization of IDE devices, which assists CMS in determining whether or not an IDE device should be covered (reimbursed) by CMS. On December 2, 2015, FDA's Center for Devices and Radiological Health (CDRH) and CMS's Coverage and Analysis Group (CAG) executed a Memorandum of Understanding (MOU) to streamline and facilitate the efficient categorization of investigational medical devices in order to support CMS's ability to make Medicare coverage (reimbursement) determinations for those investigational devices. The MOU noted the need for FDA and CMS to revise their shared understanding regarding categorization. This guidance document is intended to implement the MOU by further explaining the framework that FDA (both CDRH and the

Center for Biologics Evaluation and Research) intends to follow for such decisions. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-1159 for "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing

and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single copies of the guidance to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Program Operations Staff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1522, Silver Spring, MD 20993-0002, 301-796-5640; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for sponsors, clinical investigators, industry, institutional review boards, and FDA staff, entitled "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions." When finalized, this draft guidance would modify FDA's current policy on categorization of IDE devices. In September 1995, the Health Care Financing Administration (now known as CMS) published a final rule and entered into an Interagency Agreement (IA) with FDA regarding reimbursement categorization of investigational devices. (60 FR 48417, September 19, 1995.) The rule at 42 CFR part 405, subpart B established that certain devices with an IDE approved by FDA (and certain services related to those devices) may be covered under Medicare, and set forth the process by which FDA would assist CMS in identifying such devices. FDA would assign a device with an FDA approved IDE to one of two categories: Experimental/Investigational (Category A) devices or Non-experimental/Investigational (Category B) devices based on the level of risk the device presented to patients. The IA set forth criteria, agreed upon by CMS and FDA, which FDA would use to categorize devices. The categorization would then be used by CMS as part of its determination of whether or not devices met the requirements for Medicare coverage under

section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. 1385y). CMS and FDA both recognized that experience in categorizing devices might require changes to the Interagency Agreement.

In the more than 20 years since the IA was signed, FDA has received a number of IDEs which do not easily fit into any of the eight subcategories identified in the IA. There have been several developments, such as: The publication of the guidance document entitled "Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies;" (Ref. 1) and a subsequent increase in submission of early feasibility studies to FDA, as well as modifications to CMS's regulation regarding IDEs (42 CFR part 405, subpart B), which have prompted FDA and CMS to revise their shared understanding regarding the categorization of IDE devices.

On December 2, 2015, FDA's CDRH and CMS's CAG executed an MOU to streamline and facilitate the efficient categorization of investigational medical devices. The MOU will become effective June 2, 2016. This guidance document is intended to implement the MOU and describes the criteria that FDA intends to use to help determine the appropriate category for a device to be studied. This guidance document also describes a pathway for changing the device category from Category A to Category B.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions." It does not establish any rights for any person and is not binding on FDA or the public. You can

use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16001 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA and CMS regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078. The collections of information in 42 CFR part 405, subpart B have been approved under OMB control number 0938-1250.

V. Reference

The following reference is on display in the Division of Dockets Management (see

ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies, available at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm279103.pdf>.

Dated: May 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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